REMARKS/ARGUMENTS

This response is submitted in response to the Office Action dated May 20, 2004. Claims 1-18, 20-31, 33 and 35-39 remain pending in the Application. Reconsideration and allowance is respectfully requested in view of the submission of the Declaration of Dr. Lobdel herewith and the remarks made below.

1. Co-pending U.S. Patent Applications and Patents Issued Therefrom

The applicant has filed an Information Disclosure Statement herewith along with the requisite fee and copies of the following patent and co-pending U.S. patent applications for the Examiner's consideration:

A. U.S. Patent Application no. 10/649,529, filed on August 27, 2003.

B. U.S. Patent Application no. 09/874,580, filed on June 5, 2001, currently allowed.

C. U.S. Patent Application no. 09/858,816, filed on May 16, 2001, issued as U.S. Patent No. 6,749,553, on June 15, 2004.

D. U.S. Patent Application no. 10/010,250, filed on November 7, 2001.

E. U.S. Patent Application no. 10/342,536, filed on January 15, 2003.

F. U.S. Patent Application no. 10/718,950, filed on November 21, 2003.

Consideration of these co-pending applications and the provision of an indication in the record by the Examiner that the Examiner has considered the patent and the co-pending applications, is hereby requested.

2. Allowable Subject Matter

The applicant hereby acknowledges the Examiner's indication of allowable subject matter with appreciation. More specifically, the Examiner has allowed claims 7-14, 21-31, 33, 36, 36, 38 and 39.

3. The 35 U.S.C. §112 Rejections

A. The 35 U.S.C. §112, first paragraph rejection

Claims 1-6 were rejected in the Office Action under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner states that the

> "claim(s) contains subject matter 'sufficient bond strength . . .body,' that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly associated with, to make and/or use the invention. It is the Examiner's position that 'sufficient bond strength' cannot be determined without undue experimentation."

See page 2 of the Office Action.

Applicant respectfully disagrees with the Examiner's position and has submitted herewith a Declaration under 37 C.F.R. §1.132 by Dr. John Lobdel to explain that there are numerous well-known standard tests for determining sufficient bond strength in the case of the attachment of radioactive material to a support. These standard tests assure that radioactive material is not inadvertently released from the radioactive source under simulated conditions of use. Additionally, the Declaration of Dr. Lobdel explains where in the application specific teachings for the bonding methods are found.

Applicant believes that the submission of this evidence should result in the withdrawal of the rejection, as the evidence clearly demonstrates that persons of ordinary skill in the art are familiar with standardized testing methods for determining if a radioactive material will detach from a support under conditions of use. As stated in the 132 Declaration, radioactive medical devices are regulated by the U.S. Food and Drug Administration through the Center for Devices and Radiological Health. (See attached ISO 2919, ISO 9978 and CDRH Guidance for Industry). One of ordinary skill in the art is aware of the Regulatory Requirements and the various means to fulfill these regulations in order to market radioactive medical devices. Moreover, numerous radioactive devices are currently on the market and thus it must be possible for a person of ordinary skill in the art to perform the tests set forth in ISO 2919 and ISO 9978. In addition, the application describes several methods to bond radioactive source material to the catheter beginning on page 13, line 6, through page 20, line 13. Thus, there would be no undue experimentation required to meet the requirements of claim 1. Favorable

consideration and withdrawal of the rejections to claims 1-6 under 35 U.S.C. § 112, first paragraph is respectfully requested.

B. The 35 U.S.C. §112, second paragraph rejection

The Examiner has rejected claims 1-6 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the applicant regards as the invention. In particular the Examiner stated "[w]ith regard to claim 1, is it unclear what "normal conditions of use" are.

Applicant respectfully disagrees with the Examiner's position. The Examiner's attention is directed to page 4, beginning at line 23. Here, the specification clearly states that the device is for delivering a radiation source to a desired treatment area in the body. Several examples are given as to the types of treatments where the device may be employed. (See page 4, lines 23-33, and page 5, lines 1-9).

More importantly, as set forth in the Declaration of Dr. John Lobdel, sealed radioactive sources must meet industry test standards set forth is ISO 2199 and ISO 9978, prior to any marketing of such devices. These tests are conducted under simulated conditions of use to determine whether radioactive material would be released from the device under normal conditions of use. This demonstrates not only that persons of ordinary skill in the art are familiar with the "normal conditions of use" for medical brachytherapy devices, but also that skilled persons have developed specialized tests for simulating normal conditions of use to ensure the safety of the medical brachytherapy devices.

Favorable consideration and withdrawal of the rejections to claims 1-6 under 35 U.S.C. § 112, second paragraph is respectfully requested.

4. The 35 USC § 103(a) Rejections

Claims 1- and 3-4 have been rejected have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. (U.S. Patent No. 5,199,939). In particular the Examiner states that

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a radioactive source, as taught by Dake et al., to provide radiation in an amount of 0.5 microcuries to about 300 curies per

> centimeter length of radioactive segment 30 to treat restenosis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

See page 3 of the May 20, 2004 Office Action.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 265 USPQ 494, 496 (CCPA 1970).

Specifically, the following underlined portions of claim 1 are not taught or suggested by Dake et al., "... a radioactive source bonded to a surface of the distal section of the catheter body with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body, the radioactive source providing radiation in an amount of from about 0.5 microcuries to about 300 curies per centimeter length of the radioactive portion of the catheter body..."

The only teaching contained in Dake et al. in relation to bonding the radioactive source to the catheter body is as follows:

> "The radioactive means...can be placed onto or into a carrier 12, or manufactured into the material of the carrier 12."

See col. 5, lines 19-22 of Dake et al. From this, it is clear that Dake et al. does not even mention bonding of the radioactive source to the surface of the catheter body. In addition, Dake et al. does not teach or suggest that the radioactive source should be bonded to the surface of the body with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body. Finally, as the Examiner admits, Dake et al. does not teach that the radioactive source should provide an amount of radiation of from about 0.5 microcuries to about 300 curies per centimeter length of the radioactive portion of the catheter body. Thus, at least three limitations of claim 1 of the present application are not taught or suggested by Dake et al. Accordingly, for this reason alone, the rejection of claim 1 under 35 U.S.C. §103(a) should be withdrawn since the Examiner has not made out a *prima facie* case of obviousness.

In addition, Dake et al. does not teach or suggest any method for bonding the radioactive material to the surface of a catheter body and thus Dake et al. does not contain an enabling disclosure for this feature of the present invention. For this additional reason, the rejection under 35 U.S.C. §103(a) should be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Claims 3 and 4 depend from claim 1 and thus are considered to be patentable over Dake et al. for the same reasons as are given above.

Favorable consideration and withdrawal of the rejections to claims 1 and 3-4 under 35 U.S.C. 103(a) is respectfully requested.

The Examiner has rejected claims 2 and 5 under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Hess (US 5,302,168). Specifically, the Examiner states

> Regarding claim 2, it would have been obvious to one of ordinary skill in the art to substitute a balloon catheter as, for example, taught by the Hess reference for the Dake et al. device wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the claimed device. Regarding claim 5, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath around the Dake et al. device as taught by Hess, for shielding the radiation source.

See page 4 of the Office Action

This rejection, however, also fails to provide any evidence that either Hess or Dake et al. teaches bonding. In fact, the Examiner noted on page 3 of the Office Action dated October 22, 2003, that, "Hess does not disclose that radioactive source 38 is attached to balloon 36 by bonding." Neither Hess nor Dake et al. provide any teaching of bonding a radioactive source to a surface of the distal section of the catheter body and the Examiner has provided no evidence that bonding radioactive material to a surface of the distal section of a catheter body with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body, is well-known.

In the previous response, it was requested that the Examiner substantiate the position that bonding a radioactive source to a surface of a distal section of a catheter with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not

detach from the catheter body, pursuant to MPEP §2144.03(C). Applicant notes that the Examiner elected not to provide such evidence.

Moreover, devices for insertion into the body employing radioactive material generally include a biocompatible coating on the outer surface thereof to prevent the radioactive material from detaching from the device during normal conditions of use. Dake et al., for example, advocates locating the radioactive material inside the distal end of the catheter body. See e.g. Fig. 9 of Dake et al. Carden, Jr. (U.S. Patent No. 5,405,309) also emphasizes the need for an outer, biocompatible coating over the radioactive material to prevent contact of the radioactive material with bodily fluids. See e.g. col. 7, lines 32-38 of Carden, Jr. In view of these facts, the Examiner's rejection is deficient in that it does not teach or suggest that one should bond radioactive material with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body, nor does the Examiner's rejection provide any teachings as to how to accomplish this goal.

Applicant submits that claims 2 and 5, which depend from claim 1 should be allowed by virtue of their dependence on independent claim l and further in view of the fact that Hess does not cure the deficiency of Dake et al. Applicant respectfully requests that the rejection to claims 2 and 5 be removed and the claims allowed.

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable in view of Carden, Jr. (U.S. 5,405,309). Carden discloses a radioactive seed or capsule to be implanted in a living body. Carden does not disclose bonding a radioactive source to the distal end of a catheter with sufficient bond strength that under normal conditions of use of the catheter, the radioactive source will not detach from the catheter body. As claim 6 depends from claim 1 and Carden, Jr. does not cure the deficiencies of Dake et al, applicant submits that the rejection of claim 6 should be withdrawn.

Claims 15 and 16 have been rejected under 35 USC 103(a) as being unpatentable over Liprie (U.S. Patent No. 5,282,781) in view of Hess, and further in view of Dake et al.

Liprie discloses a device including a source wire 10 with a plug 27 to provide access to the cavity wherein radioactive core 25 is placed (shown in Fig. 1). Hess discloses a device 10 having a distal end 18 with tip 20 and a wire wound housing 22 with a sheath 24 that is retracted in order to expose a window cut 32 which permits exposure of the radioactive source 30. The

rejection argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made, "to have provided a retractable sheath in the device of Liprie for radiation shielding as taught by Hess." Applicant contends that one of ordinary skill in the art would not have looked to Hess since having a retractable shield in Liprie would have been undesirable.

Liprie's device is designed so that radioactive core 25 is within hollow tubing 12. As the rejection points out, on pages 4 and 5, "carrier 10 is placed within conventional tubing as a protective sheath for radiation treatment of a body." In other words, since the hollow tubing 12 of Liprie is the "sheath," it would have to be the portion of Liprie's device that is retractable. However, this is not desirable in Liprie's device. Liprie's device is designed so that the radioactive source is effective without removal from the hollow tubing 12. Indeed, preventing the exposure of the radioactive core 25 to the body is the purpose of hollow tubing 12. One of the reasons for the structure of Liprie's device is due to the brittleness of the core that tends to cause flaking and the high dosage of the source. See col. 3, lines 52-54, and lines 65-68. The radioactive core 25 intended for use in Liprie's device would therefore be too strong and too brittle to permit open exposure. Retracting a portion of the sheath would thus be undesirable in the device of Liprie for at least these reasons. Furthermore, open exposure of the radioactive source used for Liprie's device may be too strong since Liprie's source is designed to compensate for shielding of radiation by the material of hollow tube 12. In fact, the purpose of the Liprie device is the delivery of high dose radioactivity to a tumor site inaccessible by surgery by means of a catheter. Thus, direct exposure of the Liprie source to the body is undesirable since, as Liprie points out, it is prone to flaking thereby increasing the risk that radioactive material may be separated from the Liprie device and be transported to other portions of the body.

Accordingly, since the proposed modification of Liprie with the retractable sheath of Hess renders Liprie unsatisfactory, in many ways, for its intended purpose, as discussed above, it cannot support a rejection under 35 U.S.C. §103(a). See e.g. MPEP 2143.01 and *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicant earnestly requests that the rejection of claim 15 be withdrawn. Applicant submits that the rejection of claims 16 should be withdrawn as well due to its dependence on claim 15.

Claims 17, 18, and 37 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie, in view of Hess and Dake et al., further in view of Leavitt et al. U.S. Patent 6,352,682. Leavitt et al. teaches locally deposited biodegradable polymer deposit as a vehicle for the immobilization of local delivery of a radionucleotide or radiopharmaceutical. (See, for example, column 1, lines 49-54) Thus, Leavitt et al. teaches placement of a radioactive material contained in a gel for deposit within a body. The gel biodegrades over time thus the radionucleotide must be carefully chosen to limit the depth of exposure in the body and to prevent the emission of particles outside the body. (See column 4, lines 12-50) One of ordinary skill in the art would not look to Leavitt et al. to develop a radioactive catheter. Thus, there is no motivation to combine Leavitt et al. with any of the cited references. Even assuming, *arguendo*, that there is some reason to combine Leavitt with the other cited references, Leavitt at al. does not solve any of the deficiencies of the cited references.

Applicant earnestly requests that the rejection of claims 17-18 and 37 be withdrawn due to their dependence on claim 15. Additionally, because claim 20 depends from claim 15, Applicant respectfully requests that the rejection to claim 20 be withdrawn.

5. Double Patenting Rejections

The Examiner has provisionally rejected claims 1-3 and 5-6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 or 2 or 3 or 14 or 15 of U.S. Patent application no. 09/858,816, which issued June 15, 2004, as U.S. Patent No. 6,749,553, in view of Hess. Applicant has filed herewith a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) over U.S. Patent no. 6,749,553 in order to obviate this rejection. Withdrawal of the obviousness-type double patenting is respectfully requested.

The Examiner has provisionally rejected claims 1 and 3-4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of co-pending application 10/010,250, in view of Dake et al. Because the claims in the co-pending application have not yet been allowed or issued and may be amended, Applicant hereby requests deferral of this rejection until such time as notice of allowance in said co-pending application is received. Applicant preserves its' right to traverse this rejection.

The Examiner has provisionally rejected claim 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of co-pending application 10/010,250 in view of Dake et al. and Hess. Because the claims in the co-pending application have not yet been allowed or issued and may be amended, Applicant hereby requests deferral of this rejection until such time as notice of allowance in said co-pending application is received. Applicant preserves its' right to traverse this rejection.

The Examiner has provisionally rejected claim 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of co-pending application 10/010,250 in view of Dake et al. and Carden, Jr. Because the claims in the co-pending application have not yet been allowed or issued and may be amended, Applicant hereby requests deferral of this rejection until such time as notice of allowance in said co-pending application is received. Applicant preserves its' right to traverse this rejection.

6. Conclusion

Applicant has made an earnest effort to place this application in condition for allowance. If the Examiner feels that a telephone interview would expedite prosecution of this patent application, the Examiner is respectfully invited to telephone the undersigned at 215-599-0600.

Respectfully submitted,

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